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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/305,738	05/06/1999	KLAUS MOSBACH	003300-357	2570

7590 01/20/2004

MORGAN & FINNEGAN LLP
345 PARK AVENUE
NEW YORK, NY 10154

EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/20/2004

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/305,738

Applicant(s)

MULLER ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2) Claims 34-38 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reason set forth in paragraph **8)** of the May 05, 2003 Office action. Applicants' arguments filed November 05, 2003 have been fully considered but they are not persuasive. Applicants have apparently misunderstood the rejection of record which is based on the fact that the antibodies of the method of use claims 34 and 35 must, of necessity, have specificity for the drug being assayed. However, the antibodies of claim 27 (from which these claims depend) do not require any particular specificity. This rejection could be overcome by inserting in claim 34, at the end of line 3), the words -- wherein the binding sites of the antibodies have specificity for the drug molecule--.

3) Claims 27-38 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the corresponding claims of U.S. Patent No. 5,959,050 for the reason set forth in paragraph **9)** of the November 05, 2003 Office action. Applicants again offer to file a terminal disclaimer upon the indication of allowable subject matter in this application.

4) Claims 27-38 are again rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mosbach (U.S. Patent No. 5,110,833) for the reasons set forth in paragraph **10)** of the May 05, 2003 Office action.

Applicants' arguments and the Sigal declaration filed November 05, 2003 have been fully considered but they are not persuasive. Contrary to applicants' characterization of the Mosbach patent, the enabling written disclosure in this reference of molecular imprint polymeric "particles of less than 25 microns" (col. 5, lines 38-40) is considered to specifically describe and therefore anticipate the claimed molecular imprint polymeric particles which have "a particle size of less than about five microns". The

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particles of the Mosbach patent have utility as column chromatography reagents (see col. 5, lines 41-47) and as immunoassay reagents (col. 3, lines 23-28), the same utility recited in instant claim 34. Mosbach further states that "if the imprinted polymers are of a lower molecular weight, these can be applied in a homogenous immunoassay" (col. 3, lines 26-28).

The Mosbach patent by itself anticipates the products of the instant claims, with no consideration of the O'Shannessy references cited by applicants being required to further evaluate the Mosbach patent. Indeed, the O'Shannessy references do not significantly add to the Mosbach disclosure. However, the following comments are made in regard to the characterization of the O'Shannessy references made in the Sigal declaration. The Sigal declaration indicates that the "fines, i.e., the particles that are substantially smaller than 25 microns" are removed from the packing material of the O'Shannessy references thus indicating that these particles have no utility. However, this is not what is specifically stated by the references. O'Shannessy (II) merely makes the following statement:

"Particles which passed through a 25-micron sieve constituted a fraction of <25 microns. In all cases, dust was removed by flotation in acetonitrile, and the particles were finally dried under vacuum."

There is no statement in the reference as to what particle size constitutes "dust". The next section of O'Shannessy (II) then describes the use of particles of <25 microns as packing for high performance liquid chromatography columns:

"Particles <25 microns were slurried by sonication in water-acetonitrile-acetic acid...and packed using the same solvent..."

{The 45-63 micron particles were "dry-packed" rather than "slurried".}

Contrary to the statement made in paragraph 15. of the Sigal declaration, clearly the <25 micron particles of O'Shannessy (II) have a utility. O'Shannessy (I) contains essentially the same disclosure as O'Shannessy (II) (see the last two paragraphs of page 145).

5) THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

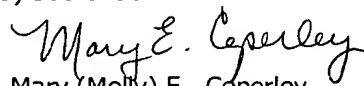
6) Since the prosecution in this application has proceeded through two final rejections which involved the same issue for appeal, applicants are encouraged to file a Notice of Appeal to further advance the prosecution of this application.

7) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (703) 308-4239. After January 27, 2004, the examiner can be reached at (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (703) 305-3399. The central fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

January 13, 2004


Mary (Molly) E. Ceperley
Primary Examiner
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